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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/158,272 09/22/98 DIAS

V 10806-64

HM12/1117

EXAMINER

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WOITACH, J

ART UNIT	PAPER NUMBER
1632	5

DATE MAILED:

11/17/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/158,272</b>	Applicant(s) <b>Dias Et. Al.</b>
	Examiner <b>Joseph Woitach</b>	Group Art Unit <b>1632</b>

Responsive to communication(s) filed on \_\_\_\_\_.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 27-52 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 27-52 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

Claims 1-26 have been cancelled, claims 27-52 have been added and are pending.

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 27-28, 31-50, 52, drawn to methods of genetic modification in animals, classified in class 435, subclass 462.
- II. Claim 29, drawn to genetic modification in plants, classified in class 435, subclass 468.
- III. Claim 30, drawn to genetic modification in microorganism, classified in class 435, subclass 471.
- IV. Claim 51, drawn to a method of gene therapy, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are independent and distinct from each other because they are directed to methods for use in either animals or plants. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as claimed are methods directed for use in different kingdoms, for instance, I are methods directed for use in animals and II are methods directed for use in plants. These methods are distinct both physically and functionally, require different process steps, reagents and

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parameters, and produce different products. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Inventions I and III are independent and distinct from each other because they are directed to methods for use in either animals or microorganisms. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as claimed are methods directed for use in different kingdoms, for instance, I are methods directed for use in animals and III are methods directed for use in microorganism. These methods are distinct both physically and functionally, require different process steps, reagents and parameters, and produce different products. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper.

Inventions II and III are independent and distinct from each other because they are directed to methods for use in either plants or microorganisms. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as claimed are methods directed for use in different kingdoms, for instance, II are methods directed for use in plants and III are methods directed for use in microorganisms. These methods are distinct both physically and functionally, require different

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process steps, reagents and parameters, and produce different products. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group III, restriction for examination purposes as indicated is proper.

Invention IV, and inventions I-III are independent and distinct, each from the other, because they are methods which possess characteristic differences in process that are distinct for each invention which can not be exchanged. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the invention of group IV is a method of gene therapy. Because these inventions are distinct for the reasons given above and the search required for Group I. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group I-III, restriction for examination purposes as indicated is proper.

The inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above invention is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of any one Group would not necessarily anticipate or make obvious any of the other groups.

For these reasons restriction for examination is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach, whose telephone number is (703) 305-3732. The examiner can normally be reached on Monday through Friday from 8:00 to 4:30 (Eastern time).

If attempts to reach the examine by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached on (703) 308-2035. The fax number for group 1600 is 1 (800)308-4242.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is (703) 308-0196.

Joseph T. Woitach



BRUCE R. CAMPELL  
PRIMARY EXAMINER  
GROUP 1800